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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,286	08/24/2001	Satoshi Omura	468-30	2354

7590 05/14/2003

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EXAMINER

NASHED, NASHAAT T

ART UNIT

PAPER NUMBER

1652


DATE MAILED: 05/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/914,286	Applicant(s) Omura et al.
Examiner Nashaat T. Nashed	Art Unit 1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 7, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Claims 1-43 are pending.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- | | |
|-----------|---|
| Group I | Claims 1-29, 31-38 and 43, drawn to a nucleic acid encoding a polyketide synthase of SEQ ID NO: 3, vector, a host cell, said polyketide synthase and a method of making the polyketide synthase, classified in Class 435, subclass 183. |
| Group II | Claims 1-29, 31-38 and 43, drawn to a nucleic acid encoding a polyketide synthase of SEQ ID NO: 4, vector, a host cell, said polyketide synthase, and a method of making said polyketide synthase, classified in Class 435, subclass 183. |
| Group III | Claims 1-29, 31-38 and 43, drawn to a nucleic acid encoding a polyketide synthase of SEQ ID NO: 5, vector, a host cell, said polyketide synthase, and a method of making said polyketide synthase, classified in Class 435, subclass 183. |
| Group IV | Claims 1-29, 31-38 and 73, drawn to a nucleic acid encoding a polyketide synthase of SEQ ID NO: 6, vector, a host cell, said polyketide synthase, and a method of making said polyketide synthase, classified in Class 435, subclass 183. |
| Group V | Claims 30 and 34-38, drawn to the nucleic acid sequence of SEQ ID NO 7, vector, a host cell, and a method of making the polypeptide encoded by the nucleic acid sequence of SEQ ID NO: 7, classified in Class 435, subclass 69.1. |
| Group VI | Claims 39-41, drawn to methods of making many chemical compounds, classified in class 435, subclass 41. Applicant must specify the chemical compound to be made. |
| Group VII | Claim 42, drawn to an altered avermectin, classified in class 435, subclass 41. |

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of the invention of Group I-IV are the nucleic acid sequences encoding the

polyketide synthases of SEQ ID NO's: 3-6. Each of the nucleic acid sequences have different structure and encodes a different protein having different structure and function, i. e., catalyzes the formation of different biochemical intermediate in the biosynthesis of avermectin. Each of Group I-IV contains claims directed to nucleic acid, polypeptide, host cell, vector and recombinant method to make the polypeptide (first use). Also, the nucleic acid sequence of SEQ ID NO: 7 is the special technical feature of the invention of Group V, which is not the same technical feature of the inventions of Groups I-IV. The inventions of Group VI are drawn to multiple independent methods of making avermectin aglycon or altered compound thereof which represent a second use for the nucleic acid of Groups I-IV. Groups I-IV contain a first use of the nucleic acid which is the use of the nucleic acid to make the polyketide synthase of SEQ ID NO's: 3-6, respectively. Thus, the invention of Group VI and those of Group I-IV do not share a special technical feature. Also, the various methods encompassed in the invention of Group VI do not share a special technical feature because each different chemical compound would require a specific modification of the nucleic acid. If applicants elect Group VI, they must specify the chemical compound to be made and the genetic modification required to make that particular chemical compound. Similarly, the invention of Group VII is drawn to multiple chemical compound which do not share a special technical feature among themselves and with the inventions of Groups I-VI because the special technical feature of the invention is the chemical compound itself. If applicants elect Group VII, they must specify the chemical compound. The election of a single compound or a single genetic modification to make a single compound in Groups VI and VII is not an election of species. It is an election of an independent invention having a lack of unity of invention among them. Thus, the inventions of Groups I-VIII and those comprised in the invention of Groups VI and VII are not so linked as to form a single general inventive concept under PCT Rule 13.1

A telephone call was made to Gary R. Tanigawa on May 9, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Nashaat T. Nashed, Ph.D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, Friday from 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Nashaat T. Nashed, Ph. D.
Primary Examiner